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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/706,325 11/03/00 ZAPATA

P-LJ 4453

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HM22/1019

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/706,325

Applicant(s)

Zapata et al

Examiner

Karen Canella

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30 days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-73 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 51-60 and 46, in part, drawn to TPBD polypeptides, chimeric polypeptides and therapeutic compositions comprising TPBD polypeptides, classified in class 530, subclass 350.

elect II. Claims 8-11, 68-73 and 46 in part, drawn to anti-TPBD antibodies, cell line producing said antibodies, and TPBD-modulating agents classified in, for example, class 424, subclass 130.1 and class 435, subclass 326.

VB III. Claims 12-24 and 27, drawn to polynucleotides encoding TPBD polypeptides, vectors, recombinant cells, oligonucleotides, kits comprising oligonucleotides, antisense nucleic acids, compositions comprising antisense nucleic acids, the recombinant expression of TPBD and primers, classified in class 536, subclasses 23.5, 24.5, 24.33, 24.31 and class 435, subclasses 69.1, 252.3, 320.1.

IV. Claim 25, drawn to a method for identifying nucleic acids encoding TPBD comprising polynucleotide hybridization, classified in class 435, subclass 6.

Wants + V. Claims 26, 48, 49, 66 and 67, drawn to methods for detecting human TPBD comprising contacting a sample with and anti-TPBD antibody, methods of diagnosing a pathology using an agent which can bind TPBD and a method of

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diagnosing cancer or assessing prognosis of cancer patients comprising contacting a test sample with an anti-TPBD antibody, classified in class 435, subclasses 7.1, 7.21, 7.23 and 7.8 and class 436, subclasses 501 and 503.

- VI. Claims 28-35, 42, 43, 50 and 62, drawn to methods for modulating a TNF family binding protein, TRAF protein, TRAF-associated protein, NF-kb, cJun, and a cell process and an activity mediated by TPBD comprising contacting a cell with an agent which modulates the activity of TPBD proteins, and methods for modulating an activity mediated by TPBD comprising contacting TPBD with an agent which modulates the activity of TPBD and a method for apoptosis comprising contacting a cell with an agent which modulates the association between TPBD and TRAF, classified in, for example, class 514, subclasses 13 and class 530, subclass 387.1.
- VII. Claim 44, drawn to a method for modulating apoptosis comprising introducing a polynucleotide encoding TPBD into a cell, classified in class 514, subclass 44.
- VIII. Claim 45, drawn to a method of modulating class switching in a B-cell comprising introducing an TPBD antisense polynucleotide into a cell, classified in class 514, subclass 44.
- IX. Claims 36, 47 in part and 65 in part, drawn to a method for modulating the activity of an oncogenic protein comprising contacting a cell with TPBD polypeptide or fragments thereof, classified in class 514, subclasses 2 and 21.

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- X. Claims 37-41, 61, 63 and 64, drawn to a method for identifying and agent that modulates the association of TPBD with TRAF, classified in class 435, subclass 7.1, 7.2 and 7.8 and class 436, subclasses 501 and 536.
- XI. Claims 47 in part and 65 in part, drawn to a method for treating abnormal cell proliferation or abnormal immunoglobulin class-switching comprising administering anti-TPBD antibodies or agents which bind to TPBD, classified, for example, in class 530, subclass 387.1.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II and III are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV-XI differ in the method objectives, method steps and parameters and in the reagents used.

Invention I is related to Inventions IX and X as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Invention I are used in the method of modulating the activity of an anocogene of Invention IX as well as in the method of

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identifying agents which modulate the association between the polypeptide of Invention I and TRAF. In addition, the polypeptide of Invention I can be used in the process to make the antibodies of Invention II.

Invention II is related to Inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the anti-TPBD antibodies and agents which bind TPBD can be used in the method of detecting TPBD of Invention V and the method of modulating the activity of TPBD of Invention VI. In addition, the antibody of Invention II can be used in a process to raise an antiidotypic antibody.

Invention III is related to Invention IV, VII and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Invention III can be used in the methods of Inventions IV, VII and VIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent

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subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

October 10, 2001



GEETHA P. BANSAL
PRIMARY EXAMINER